

REMARKS

In the Office Action, claims 1-3 and 5-20 have been rejected for being unpatentable over U.S. Patent No. 5,147,355 to Friedman et al. in view of U.S. Patent No. 6,235,019 to Lehmann et al. Claim 4 has been rejected for being unpatentable over Friedman et al. in view of Lehmann et al. and in further view of U.S. Patent No. 5,452,582 to Longsworth.

In response to the Office Action, independent claims 1, 10 and 16 have been amended. Specifically, each of these independent claims has been amended to require a means for, or step of, minimizing both the tip temperature and the required working pressure of the heat transfer system. Support for these amendments is found in the specification on page 5 at lines 6 through 22 and beginning on page 9 at line 21 and continuing onto page 10 through line 13.

The claims have been amended to improve the readability of the claims, to more clearly define the structure of the invention, and to point out the features that distinguish this invention over the cited art. Claims 1-20 remain pending.

Rejections under 35 U.S.C. § 103

Claims 1-3 and 5-20 have been rejected under 35 U.S.C. § 103 for being unpatentable over Friedman et al. in view of Lehmann et al. Claim 4 has been rejected for being unpatentable over Friedman et al. in view of Lehmann et al. and in further view of Longsworth.

While the Examiner does not identify any motivation or suggestion to combine the references in the references themselves, he states that it would have been obvious to modify the cooling probe of Friedman et al. by using a temperature probe to control the flow of cryogenic fluid as in Lehmann et al.

Despite the lack of motivation to combine the references, in order to more clearly present the unique features of the invention, the Applicants have amended independent claims 1, 10 and 16 to include the requirement of a means for, or step of, minimizing both the tip temperature and the required working pressure of the heat transfer system. Further, independent method claim 16 has been amended to require a step of selectively increasing and decreasing the working pressure until predetermined conditions are met. None of the cited references disclose such means or steps.

Specifically, Friedman et al., whose device lacks any temperature sensor, fail to disclose any means for minimizing the tip temperature or the working pressure of the heat transfer system. As disclosed in Friedman et al., the flow of cryogenic fluid to its catheter tip may be controlled in two circumstances. First, the flow of cryogenic fluid to the tip is controllable to provide reversible cooling of the tissue adjacent the tip portion to prevent irreversible tissue damage (column 2, lines 45-48). Second, the flow of cryogenic fluid to the tip may be terminated in response to sensed changes in the electrical activity of the targeted tissue (column 4, lines 9-31). Unlike the claimed invention, in neither situation does the Friedman et al. device provide for minimizing even the tip temperature, let alone the working pressure, of the heat transfer system. Instead, in the first situation, the Friedman et al. device increases its tip temperature so

that irreversible cooling does not occur. In the second situation, the flow is stopped completely, thereby leading to the catheter tip's inevitable return to ambient temperature. Further, Friedman et al. do not provide any motivation to identify and attain the minimal tip temperature while providing the lowest working pressure necessary.

Turning to the Lehmann et al. reference, it lacks any disclosure or suggestion of means for minimizing the tip temperature and the working pressure of the heat transfer system. Lehmann et al. disclose the use of temperature sensors in communication with a controller to regulate or terminate the flow of cryogenic fluid "when a predetermined temperature at a selected point or points on or within the catheter is/are obtained" (column 3, lines 44-53). While temperature control is envisioned by Lehmann et al., they do not disclose means or steps for minimizing the tip temperature. Moreover, unlike the claimed invention, Lehmann et al. fail to disclose the minimization of the catheter's working pressure concurrent with the minimization of the tip temperature.

In the Office Action, the Longsworth reference is cited as providing a pressure regulator. As shown in its Fig. 6 and the related description, the Longsworth reference fails to disclose any ongoing modulation of its pressure regulators. Unlike the claims of the present invention, Longsworth does not disclose or suggest the minimization of the tip temperature or working pressure.

In contrast to the cited prior art, all of the Applicants' claims include the requirement of means or steps for minimizing the tip temperature and the working pressure, which results in an efficient operation of the heat transfer system that is

neither disclosed nor suggested in the cited prior art.

In light of the arguments presented above for distinguishing the claimed present invention from the cited references, Attorney for Applicants respectively submits that no combination of the cited references discloses or suggests the claimed invention. Consequently, Applicants contend that claims 1-20 are nonobvious with respect to the combination of cited references.

The references cited by the Examiner, but not relied on for the rejection of claims, have been noted.

In conclusion, Applicants respectfully assert that claims 1-20 are patentable for the reasons set forth above, and that the application is now in a condition for allowance. Accordingly, an early notice of allowance is respectfully requested. The Examiner is requested to call the undersigned at 619-688-1300 for any reason that would advance the instant application to issue.

Dated this 27th day of September, 2005.

Respectfully submitted,



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Serial No. 10/797,398

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David J. Lentz et al.)
Serial No: 10/797,398) Art Unit
Filed: March 10, 2004) 3744
For: PRESSURE-TEMPERATURE CONTROL FOR)
A CRYOABLATION CATHETER SYSTEM)
Examiner: William Charles Doerrler)
Customer No: 23862)
Attorney Docket: 11350.31)

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27th day of September, 2005.

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Transmitted: Transmittal of Amendment in Response to the Office Action dated April 29, 2005; Petition for Extension of Time and Check for Petition for Extension of Time.

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